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EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1743	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,884	BERLIN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *15-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 31-35 drawn to a method for analysis of molecules in a resonant spectroscopic analysis chamber with Raman spectroscopy, classified in class 436, subclass 164.

II. Claims 15-23, drawn to an analysis chamber, classified in class 422, subclass 58.

III. Claims 24-30, drawn to a method for analysis of a single molecule with a coherent Raman spectroscopy, classified in class 436, subclass 172.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method can be performed with a resonant spectroscopic analysis chamber, which comprises a surface for conducting stimulated surface-enhanced Raman spectroscopy, and the apparatus can be used for conducting conventional Raman spectroscopy (see e.g. Keilbach et al., EP 814,333 A2, IDS).

Inventions I-II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. Inventions of Groups I and III refer to completely different types of Raman spectroscopy, with the method of Group III performed with a different apparatus then the method of Group I.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Group III, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Michael Reed on 10/20/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14 and 31-35.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

3. Drawings are objected to as not representing the essence of the invention in a clear form.

Figure 1 demonstrates general steps of the method disclosed. While the step of irradiating sample is an active step of the method, the step of scattering radiation from the sample is not, since scattering radiation is an intrinsic feature of the sample. Also, the step of resonating scattered radiation can follow the step of scattering the radiation only if the sample is placed into or close to a resonance cavity, which should occur before the experiment starts. The step of "irradiating scattered radiation from the chamber" is completely unclear, as it will be discussed further.

Figure 2 demonstrates a general spectroscopic system for the method disclosed. It seems however that Figure 2 represents a general scheme for any spectroscopic analyzer utilizing scattered radiation. No inventive features are shown in the Figure. If this is a well-known scheme in the art, Figure 2 should be labeled -- Prior Art --. If there are new features of the apparatus, they should be clearly indicated. Also, if a sample 230 contains just one molecule, according to the specification, it is not clear, how this molecule is hold in the spectroscopic analysis chamber 250 during analysis. Description of Figure 2 in the specification on page 7 reciting "an aqueous solution of a diluted nucleic acid derivative" should be rewritten as "a diluted aqueous solution of a nucleic acid derivative", since it is the solution that is diluted, rather than a DNA derivative. Also, Figure 2 should demonstrate the means, which separate just one molecule from such diluted solution to place it in the chamber 250 to have the sample

disclosed in the specification and claims, i.e. the sample comprising just one molecule. No such means are shown on the Figure. The specification discloses a resonance cavity in the analysis chamber into which a molecule should be placed in order to perform the method disclosed, which basically coincides with the analysis chamber except for the mirrors. Again, it is not clear from the drawing, how a single molecule is held in the cavity during the analysis. Especially it is not clear, how the sample can be flowed continuously into the chamber, if the sample is supposed to contain just one molecule.

From the specification it appears that the resonance cavity is a required feature of the system for performing the method disclosed, which means that it should be indicated separately on Figure 2. Moreover, its structure is predetermined by several parameters, including the resonance frequency and the frequency of the detected radiation. This requires preliminary analysis of the same analytes in order to obtain these frequencies. Only then the enabled structure depicted on Figure 2 can be constructed. The specific relations between the cavity height and analyte frequencies need to be indicated on the Figure.

Figure 4 is referred to as representing Stokes Raman spectra of diluted samples of four DNA nucleotides "according to embodiments of the invention". Which embodiments are meant here? The invention is supposed to be directed toward stimulated enhanced Raman spectroscopy, while Figure 4 demonstrates spontaneous Raman spectra, performed by a standard Raman technique. It is not clear, which inventive features of which embodiments are meant in the above expression.

Remaining drawings refer to non-elected inventions and are not considered in the present Office action.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Stimulated and coherent anti-Stokes Raman spectroscopic method and apparatus for detecting single molecules".

5. The abstract of the disclosure is objected to because a), the first sentence is non-descriptive and not informative; b), the abstract is written in a language of multiple possible variations of Raman techniques without any emphasis on the inventive features of the method disclosed. It makes it unclear, as to which inventive features of the instant application the abstract discloses. Correction is required. See MPEP § 608.01(b).

6. There is a typo in the disclosure, page 5, line 6, "analyzing a plurality **if** [should be *of*] molecules".

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The specification is objected to as not containing "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art" to practice the method in its best mode.

The specification appears to be a mix of discussion of the prior art and well-known theoretical concepts of various forms of Raman spectroscopy along with disclosing possible structures of resonant chambers for different Raman techniques based on these theoretical concepts. According to the specification the chambers can be adapted for analysis of plural molecules and single molecules, including nucleotides of DNA. However, no ways of preparing samples containing single molecules of DNA (not mentioning single molecules of nucleotides) are disclosed in the specification, which makes it unclear, on how such samples can be prepared. The only real experiments represented in the specification refer to standard spontaneous Raman spectroscopy of four nucleotides, which cannot be considered inventive features of the method, since this technique is well known in the art.

The language and structure of the specification disclosing variety of possible embodiments of Raman techniques along with the resonance chambers together with known methods of the prior art makes it difficult to understand the inventive features of the method and system disclosed. The definition "resonance enhanced stimulated Raman spectroscopy" is not represented in such clear terms so as to differentiate it from stimulated "surface-enhanced resonance Raman scattering" (SERRS), the application of which for detection of single DNA

molecules is also well known and documented (see e.g. Graham et al., Anal. Chem., 1997). The same is true for the definition of "resonant spectroscopic analysis chamber", which is not clear from the specification. Referring to Figure 15 (page 3), which "shows an exemplary apparatus and method for nucleic acid sequencing" by all possible Raman spectroscopy techniques, i.e. SERS, SERRS, CARS, and "resonance enhanced Raman spectroscopy" raises a question of how can all these different methods be performed with the same apparatus?

On page 6, line 10, the disclosure reads "irradiating or transmitting the scattered radiation from the chamber". While the term "transmitting" in "transmitting the scattered radiation from the chamber" can be easily understood, it is not clear, what "irradiating the scattered radiation" might be. According to Merriam-Webster On-Line Dictionary, "irradiate" means "to cast rays of light upon" or "to affect or treat by radiant energy (as heat); *specifically* : to treat by exposure to radiation". It is not apparent what is meant by the expression "irradiating the radiation".

It seems that constructing the inventive spectroscopic system for performing the claimed method depicted on Figures 5 and 6 requires preliminary knowledge of exactly the same parameters that are supposed to be obtained by the method, e.g. "a wavelength of an inelastically scattered radiation of a molecule of interest" (page 16). This makes it unapparent how such system can be constructed.

It is unclear, if coherent anti-Stokes Raman spectroscopy (CARS) for detecting a single molecule requires a specific device or specific experiment set-up. What is disclosed on page 25 is a conventional CARS.

Furthermore, the only other examples of real Raman experiments shown on Figures 16-21 refer to SERS technique, which is well known and documented as the method for detecting single DNA molecules. The examples make it unclear, if SERS is considered one of the embodiments of the instant method. Figure 4 refers to "Stokes Raman spectra for dilute aqueous solutions of four DNA nucleotides, according to embodiments of the invention". However, it is not clear, which specific embodiments are meant here, and hence which specific Raman spectroscopy experiments Figure 4 illustrates.

Thus, it is not clear, which specific inventive features of Raman spectroscopy are disclosed in the specification, and which specific devices are required for performing different Raman techniques.

In conclusion, the specification is written in such a vague language regarding the inventive features of methods and apparatus for detecting single molecules by Raman spectroscopy, that it is difficult to apprehend the essence of the invention.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 31-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for analyzing structurally similar molecules for which parameters of scattered radiation are approximately known, does not reasonably provide enablement for any other molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The suggested spectroscopic devices for performing the method recited in claims 1-8 and 31-35 disclosed in the specification require preliminary knowledge of at least "a wavelength of an inelastically scattered radiation of a molecule of interest", not mentioning "the frequency of the particular radiation to be resonated in the chamber" (page 14).

Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose the ways of preparing a sample containing a single molecule, which is placed into the resonance chamber for performing resonance Raman spectroscopy analysis. The prior art teaches detecting scattered radiation from single molecules; however, it does not teach preparing samples containing single molecules. The specification does not disclose any working examples of such experiments. Also, no examples of real experiments conducted in the resonance chambers of various embodiments disclosed in the specification are represented in the disclosure.

Moreover, it follows from the specification that vibration energies of the molecule should be *a priori* known before constructing the resonance chamber recited in the claims. It is not demonstrated by any example of how different molecules can be detected in the same resonance chamber.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6 and 31 recite "a resonant spectroscopic analysis chamber" or "a micro-sized resonant spectroscopic analysis chamber". The specification does not disclose specifically what this chamber is, and if the chamber should have different structure for different types of Raman spectroscopy, as well as for different molecules (since its parameters are defined by the optical properties of the molecule). It is not clear, if stimulated "surface-enhanced resonance Raman scattering" (SERRS) is performed in such chamber, and therefore the chamber should be designed correspondingly. It is no clear, if any enhanced resonance Raman spectroscopy can be considered "stimulated" Raman spectroscopy; if it is not, it is not clear, what type of Raman spectroscopy is utilized for the method of claims 1 and 6.

Claim 9 is not clear as to which specific method it recites, and what is the purpose of the method. It is not clear, why "scattering radiation from the sample" is considered an active step of the method, when "scattering the radiation" is an intrinsic property of the molecule. The same is true for "resonating the scattered radiation": if the molecule is placed in the "resonance chamber", as recited in the first step, then the resonance should occur inherently to the method; it is not an active step which can be controlled by the practitioner. Moreover, it is not apparent, how "resonating the scattered radiation" can occur for any molecule, if the resonance condition is specific for each molecule, and thus the "resonance chamber" can be designed for specific molecules having similar vibrational states.

Claim 9 recites "a resonance chamber". It is not clear, if it is a different chamber from the chambers recited in claim 1 and 6.

It is completely unclear, what the expression "irradiating the scattered radiation from the chamber" might mean. Is this "transmitting the scattered radiation from the chamber"? The expression "irradiating the radiation" is technically incorrect, as it was indicated earlier.

Claim 10 is not clear regarding the method steps. If the second step comprises "reflecting the inelastically scattered radiation with a multilayer dielectric mirror containing a layer having a thickness that is based on a wavelength of the inelastically scattered radiation for the molecule", does it mean that this wavelength should be *a priori* known so that the specific resonance chamber could be constructed? If the wavelength of the inelastically scattered radiation is already known, then why should it be measured? Also, claim 10 repeats a technically incorrect expression "irradiating the scattered radiation".

Claim 12 is not clear as to how irradiating the sample with the resonated radiation is performed. If the sample is located in the resonance chamber recited in claim 9, then irradiating the sample with the resonated radiation is an intrinsic feature of the method recited in claim 9. If there is an additional source of such radiation, so that irradiating the sample with this radiation can be controlled, then it should be recited in the claim.

Claim 13 is completely unclear as to what is irradiated with what. What is meant by "irradiating the sample with a first radiation having a first frequency with a second radiation having a second frequency"?

Claim 32 is not clear as to which particular limitation to the method it claims. If the sample is irradiated with an appropriate frequency and is placed in the "resonant spectroscopic analysis chamber", "resonating inelastically scattered radiation" is an intrinsic feature of the method due to the design of the chamber. Therefore, it is not clear, what is the active step of the method recited in the claim?

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 1-2, 6-8 and 31-33** are rejected under 35 U.S.C. 102(a) as being anticipated by Maleki et al. (NASA TECH BRIEF, November 2001, IDS).

Maleki disclose a method for detecting a single molecule placed in a resonant spectroscopic analysis chamber by Raman spectroscopy using resonance inelastically scattered radiation.

13. **Claims 1, 2 and 31** are rejected under 35 U.S.C. 102(b) as being anticipated by any of Graham et al. (Anal. Chem., 1997), Xie et al. (Annu. Rev. Phys. Chem., 1998) or Kneipp et al. (Chem. Rev., 1999).

Graham teaches "selective detection of deoxyribonucleic acid at ultralow concentrations by SERRS" (Title), with SERRS being a resonance enhanced Raman spectroscopy.

Xie reviews "optical studies of single molecules at room temperature" (Title) with detailed description of SERS and SERRS studies of single molecules (pages 457-460).

Kneipp reviews "ultrasensitive chemical analysis by Raman spectroscopy" including single-molecule SERS and SERRS techniques.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. **Claims 3-5 and 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maleki in view of Graham.

Although Maleki does not specifically teach the method for detecting single or plural DNA molecules, Maleki emphasized that the disclosed sensors could be "especially useful in biochemical and biomedical applications".

Graham teaches detecting single DNA by resonance enhanced Raman spectroscopy (SERRS).

It would have been obvious for any person skilled in the art to apply Maleki's method to single DNA in the same way as taught by Graham, since Maleki emphasized potential use of disclosed sensors for biochemical and biomedical applications, with DNA being one of the most important objects of these applications.

16. **Claims 1-8 and 31-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo-Dinh (US 5,306,403, IDS) in view of Graham.

Vo-Dinh discloses a method and "Raman-based system for DNA sequencing-mapping and other separation" with the method utilizing a resonant spectroscopic analysis chamber ("enclosure") 22 comprising substrates coated with a SERS-active coating for SERS analysis of separated DNA fragments. "The coating may extend the full length of the enclosure so that the length of the enclosure can be scanned during separation using one or more SERS spectrometer devices to make real time measurements" (col. 5, lines 5-18).

Vo-Dinh does not specifically teach detecting resonance enhanced Raman spectroscopy and micro-sized chamber.

Graham teaches a resonance enhanced Raman spectroscopy (SERRS) of single DNA molecules.

It would have been obvious for anyone of ordinary skill to modify Vo-Dinh's method and apparatus with Graham's SERRA technique and decreasing the size of the resonant chamber to a micro size, because Graham emphasizes advantages of SERRA over SERA regarding sensitivity of the method, with detection of a single molecule obviously requiring a micro-size resonant chamber.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Castro et al. (Anal. Chem., 1993)* discloses "fluorescence detection and size measurement of single DNA molecules" (Title); *Otto et al. (Inter. J. Vibrat. Spectr., 1998)* review "progress in instrumentation for Raman micro-spectroscopy and Raman imaging for cellular biophysics" (Title); *Hill et al. (J. Opt. Soc. Am. B, 1999)* disclose "fluorescence image of a single molecule in a microsphere: model" (Title); *Hennrich et al. (Phys. Rev. Lett., 2000)* disclose "vacuum stimulated Raman scattering based on adiabatic passage in a high-finesse optical cavity" (Title); *Cheng et al. (Biophys. J., July 2002)* disclose "laser-scanning coherent anti-Stokes Raman scattering microscopy and application to cell biology" (Title); *Cheng et al. (J. Phys. Chem. B, August 2002)* disclose "multiplex coherent anti-Stokes Raman scattering microspectroscopy and study of lipid vesicles" (Title).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
11/15/04